PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: PAUL BIANCO
FLEIT GIBBONS GUTMAN BONGINI & BIANCO
21355 EAST DIXIE HIGHWAY, SUITE 115
MIAMI, FL 33180

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 29 APR 2010
Applicant's or agent's file reference 782-P10-048	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2010/025263	International filing date *(day/month/year)* 24 February 2010
Applicant P TECH, LLC	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 782-P10-048	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2010/025263	International filing date *(day/month/year)* 24 February 2010	(Earliest) Priority Date *(day/month/year)* 24 February 2009
Applicant P-TECH, LLC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the language, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 4

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/025263

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/08 (2010.01)
USPC - 606/213
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/08 (2010.01)
USPC - 606/213

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2009/0024161 A1 (BONUTTI et al) 22 January 2009 (22.01.2009) entire document	1-66, 68-71 ---------- 67
Y	WO 95/31941 A (ALACREU et al) 30 November 1995 (30.11.1995) entire document	67

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 April 2010	29 APR 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

From the
INTERNATIONAL SEARCHING AUTHORITY

To: PAUL BIANCO
FLEIT GIBBONS GUTMAN BONGINI & BIANCO
21355 EAST DIXIE HIGHWAY, SUITE 115
MIAMI, FL 33180

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* 29 APR 2010
Applicant's or agent's file reference 782-P10-048	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/025263	24 February 2010	24 February 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/08 (2010.01)
USPC - 606/213

Applicant P TECH, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	13 April 2010	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025263

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2010/025263

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	61, 67	YES
	Claims	1-60, 62-66, 68-71	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-71	NO
Industrial applicability (IA)	Claims	1-71	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-60, 62-66 and 68-71 lack novelty under PCT Article 33(2) as being anticipated by Bonutti et al., (Hereinafter referred to as "Bonutti").

Referring to claim 1, Bonutti discloses a method of utilizing a bondable material (802 and 850; Figs. 34 and 38) to position a fastening implant (840 in conjunction with 800; 2034 and 2008; Figs. 33 and 55-56) in a body (882; Paras. [0447-0451]), said method comprising the steps of: engaging an end effector (804; Fig. 33) and at least a trailing end (the end near element 810; Fig. 33) of the fastening implant (Fig. 34); passing at least a portion of the end effector and the fastening implant into the body (Figs. 34 and 40A); positioning at least a leading end (the end near element 820; Fig. 33) of the fastening implant adjacent the bondable material (Fig. 34); applying vibratory energy to at least the trailing end (Paras. [0447-0448]), thereby transmitting vibratory energy to the leading end to heat at least a portion of the bondable material in contact with the leading end and embed at least a portion of the leading end into the bondable material (Paras. [0447-0448]); disengaging the end effector from the trailing end (Par. [0452]), and enclosing the fastening implant in the body (Fig. 37).

Referring to claim 2, Bonutti discloses wherein the bondable material is polymethyl methacrylate (bondable material 850 or bone cement 2140; Paras. [0418], [0434] and [0455]).

Referring to claim 3, Bonutti discloses wherein at least a portion of the fastening implant (fastener 800) is bonded into the bondable material (Figs. 33-34 and Par. [0447]).

Referring to claim 4, Bonutti discloses wherein the bondable material is substantially hard before application of energy and at least a portion of the bondable material softens during the application of vibratory energy (Par. [0447]).

Referring to claim 5, Bonutti discloses wherein at least a portion of the bondable material (850; Fig. 38) flows into the fastening implant (Fig. 39) to secure the at least a portion (804) of the fastening implant to the bondable material (Figs. 38-39; Paras. [0455]).

Referring to claim 6, Bonutti discloses wherein disengaging includes rotationally disengaging the end effector (804) from the fastening implant (800; Figs. 33-34 and 37-38).

Referring to claim 7, Bonutti discloses wherein the fastening implant includes at least a portion of titanium (Par. [0206]).

Referring to claim 8, Bonutti discloses wherein the fastening implant includes at least a portion of at least one of PEEK and PLLA (Paras. [0340] and [0396-0397]).

Referring to claim 9, Bonutti discloses wherein the fastening implant includes at least a portion of titanium (Par. [0409]) and at least a portion of a polymer (the implant can be coated with a layer of bondable polymer, such as PEEK or PLLA; Paras. [0208] and [0213]).

Referring to claim 10, Bonutti discloses wherein vibratory energy includes ultrasonic energy (Par. [0201]).

Referring to claim 11, Bonutti discloses wherein the fastening implant is positioned adjacent a spine (2000; Figs. 55-56, 73 and 74A-74B) of the body to stabilize at least a portion of the spine (Paras. [0460] and [0713]).

Referring to claim 12, Bonutti discloses wherein the fastening implant stabilizes a bone (Figs. 40-40A) of a body by embedding in a previously hardened bondable material adjacent to the bone (Paras. [0193], [0235], [0343] and [0447]).

Referring to claim 13, Bonutti discloses the method of claim 1 wherein the end effector (804) is disengaged from the fastening implant when the bondable material cools and the fastening implant is left in the body (800; Figs. 33-34 and 37-38; Paras. [0339], [0349], [0366] and [0708]).

Referring to claim 14, Bonutti discloses wherein the fastening implant is positioned relative to a supporting implant, the supporting implant including a plate (plates 884, 1004, 1522 and 4100; Figs. 23, 40A, 44 and 49; Paras. [0511], [0652], [0663] and [0666]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Referring to claim 15, Bonutti discloses a method of utilizing a bondable material (802 and 850; Figs. 34 and 38) adjacent a tissue in a body (882; Paras. [0447-0451]), said method comprising the steps of: engaging an embedding implant (800 in conjunction with screw 840; 2034 and 2008; Figs. 33 and 55-56) and an end effector (804; Fig. 33); passing the embedding implant and at least a portion of the end effector into the body (Figs. 34 and 40A); positioning the embedding implant adjacent the bondable material (the end near element 820; Figs. 33-34); applying vibratory energy to the embedding implant to embed the embedding implant into at least a portion of the bondable material (Paras. [0447-0448]); and engaging a fastening implant (840) with the embedding implant to secure the tissue (Figs. 40-40A), and enclosing the fastening implant and embedding implant in the body (Fig. 40A).

Referring to claim 16, see claim 3 above.

Referring to claim 17, see claim 2 above.

Referring to claim 18, see claim 10 above.

Referring to claim 19, Bonutti discloses wherein the bondable material has previously polymerized before positioning the embedding implant (Paras.[0343], [0447] and [0662]; embedded implant 800 can be embedded within a previously solidified bone bondable material 802).

Referring to claim 20, Bonutti discloses wherein bondable material flows around the fastening implant (stents 3500 and 3504) during application of vibratory energy (Paras. [0774]).

Referring to claim 21, see claim 5 above.

Referring to claim 22, Bonutti discloses a method of utilizing a bondable material (802 and 850; Figs. 34 and 38) adjacent a tissue in a body (882; Paras. [0447-0451]), said method comprising the steps of: engaging an embedding implant (800 in conjunction with screw 840 and 2034 and 2008; Figs. 33 and 55-56) and an end effector (804; Fig. 33); passing the embedding implant and at least a portion of the end effector into the body (Figs. 34 and 40A); positioning the embedding implant adjacent the bondable material (the end near element 820; Figs. 33-34); applying vibratory energy to the embedding implant to embed the embedding implant into at least a portion of the bondable material (Paras. [0447-0448]); positioning a supporting implant (884; Fig. 40A) adjacent the tissue; engaging a fastening implant (840) and the embedding implant to secure the supporting implant adjacent the tissue (Par. [0668]); and enclosing the fastening implant and embedding implant in the body (Fig. 40).

Referring to claim 23, Bonutti discloses wherein the embedding implant is bonded to the bondable material (Par. [0447]; embedded implant 800 can be embedded within a previously solidified bone bondable material 802).

Referring to claim 24, see claim 2 above.

Referring to claim 25, see claim 10 above.

Referring to claim 26, see claim 19 above.

Referring to claim 27, see claim 20 above.

Referring to claim 28, see claim 5 above.

Referring to claim 29, Bonutti discloses wherein the supporting implant includes a plate (plates 1522 and 4100; Figs. 23 and 49: Paras. [0511] and [0652]).

Referring to claim 30, Bonutti discloses wherein the tissue includes a bone of the body (1402; Fig. 47A).

Referring to claim 31, Bonutti discloses wherein the tissue includes at least a portion of a spine (2000) of the body (Figs. 55-56).

Referring to claim 32, Bonutti discloses a method to facilitate bonding of an implant (800 in conjunction with screw 840 and 2034 and 2008; Figs. 33 and 55-56) and bondable material (850; Fig. 38) in a body (882; Paras. [0447-0451]), said method comprising the steps of: passing the implant and at least a portion of an end effector (804; Fig. 33) into the body (Figs. 34 and 40A); positioning at least a portion the implant in bondable material (Fig. 33), the bondable material being malleable (Par. [0648]); engaging the end effector and implant (Figs. 33-34); applying vibratory energy to the implant to increase the solidification of the bondable material (Paras. [0447-0448]); and enclosing the implant in the body (Fig. 40).

~~Referring to claim 33, Bonutti discloses the method of claim 32 wherein the bondable material is substantially solidified while the end~~ effector and implant are engaged (Figs. 33-34 and 37-38; Paras. [0339], [0349], [0366] and [0708]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025263

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Referring to claim 34, see claim 2 above.

Referring to claim 35, see claim 10 above.

Referring to claim 36, Bonutti discloses which further includes the step of disengaging the end effector after the polymerization of the bondable material has been increased (Paras. [0339], [0349], [0366] and [0708]).

Referring to claim 37, see claim 20 above.

Referring to claim 38, see claim 5 above.

Referring to claim 39, Bonutti discloses wherein the implant includes an intramedullary rod (880; Fig. 40A).

Referring to claim 40, Bonutti discloses a fastening system (Figs. 33 and 55-56) implantable in a body (882; Paras. [0447-0451]), comprising: a fastening implant (800 in conjunction with screw 840; and 300; Fig. 19) including a leading end (the end near element 820; Fig. 33) and a trailing end (the end near element 810; Fig. 33), said fastening implant fabricated with a material operative to conduct ultrasonic vibratory energy from said trailing end to e portion of said fastening implant eway from said trailing end (Paras. [0418], [0434] and [0455]), whereby when a portion of said fastening implant contacts a bondable material (802 and 850; Figs. 34 and 38) connected to the body and ultrasonic vibratory energy is applied to said trailing end (Paras. [0447-0448]), the bondable material attached to the body may be made flowable (Par. [0455]), and whereby after said ultrasonic vibratory energy is no longer applied to said trailing end, the bondable material may no longer be flowable, the fastening implant thereby connected to the bondable material and the body (Paras. [0447-0448] and [0455-0456]).

Referring to claim 41, Bonutti discloses the system further including the bondable material (802; Par. [0451]; Fig. 34).

Referring to claim 42, see claim 2 above.

Referring to claim 43, see claim 19 above.

Referring to claim 45, Bonutti discloses wherein seid fastening implent includes a channel (810 end 844; Figs. 33 and 35) extending from en outside surface of said fastening implant to an interior of said fastening implant (Figs. 33 and 35), whereby when a portion of said fastening implant contacts a bondable material (802 and 850) connected to the body and ultrasonic vibretory energy is applied to said trailing end (Paras. [0447-0448] and [0455-0456]), the bondable material attached to the body may be made flowable and able to enter said channel (Figs. 34 and 37-39; Pares. [0447-0448] and [0455-0456]), and whereby after said ultrasonic vibratory energy is no longer applied to said trailing end, the bondable material may no longer be flowable, the fastening implant thereby connected to the bondable material end the body (Paras. [0447-0448] and [0455-0456]).

Referring to claim 46, Bonutti discloses wherein said bondable material is warmed and softened when in contact with said fastening implent and ultrasonic vibratory energy is applied to said trailing end (Peras. [0447-0448] and [0455-0456]), whereby said bondable material flows into said channel (Fig. 39), and whereby said bondable material cools and hardens after ultrasonic vibratory energy is no longer epplied, said bondable material thereby becoming connected to the body and said fastening implant (Paras. [0447-0448] and [0455-0456]).

Referring to claim 47, Bonutti discloses further including an end effector (804; Fig. 33) operative to engage said fastening implant and apply vibratory energy to said fastening implant (Figs. 34 and 40A; Par. [0452]).

Referring to claim 48, Bonutti discloses further including a therapeutic implant (plate 884) connectable to said fastening implant in the body (Fig. 40A).

Referring to claim 49, Bonutti discloses further including a connecting implant (840) operative to connect said fastening implant and said therapeutic implant (Fig. 40A).

Referring to claim 50, Bonutti discloses wherein said therapeutic implant is selected from the group consisting of internal bone plate, external bone plate, spinal plate, wedge, cushion, pad, biocompatible support used for stabilization of tissue and/or implants (plates 884, 1004, 1522 and 4100; Figs. 23, 40A, 44, 49 and 74; Paras. [0511], [0652], [0663] and [0666]).

Referring to claim 51, Bonutti discloses wherein said therapeutic implant is an intramedullary device (880; Fig. 40).

Referring to claim 52, Bonutti discloses further including a bondable material (802 and 850; Figs. 34 and 38) operative to flow and connect to said fastening implant and said intramedullary device when said fastening implant is placed into contact with said bondable material adjacent said intramedullary device (Figs. 39-40 and 40A), and vibratory energy is applied to said fastening implant, said bondable material thereby operative to retain said intramedullary device and said fastening implant within the body (Paras. [0663-0664]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025263

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Referring to claim 53, Bonutti discloses wherein said bondable material is malleable, and said malleability is reduced after ultrasonic vibratory energy is no longer applied to said fastening implant (Paras. [0199] and [0396-0397]).

Referring to claim 54, see claim 7 above.

Referring to claim 55, see claim 8 above.

Referring to claim 56, Bonutti discloses wherein at least a portion of said fastening implant is coated with a bondable material operative to soften upon the application of ultrasonic vibratory energy (the implant can be coated with a layer of bondable polymer, such as PEEK or PLLA; Paras. [0208] and [0213]; Figs. 48-49; Paras. [0506-0509]).

Referring to claim 57, Bonutti discloses wherein said channel extends longitudinally along an interior portion of said fastening implant (Figs. 33, 35 and 39), and is operative to contain bondable material displaced from a position exterior to said fastening implant to a position in the interior of said fastening implant (Figs. 38-39).

Referring to claim 58, Bonutti discloses wherein said fastening implant includes a metallic rod (the bondable material 850 is a rod) coated with a bondable material operative to soften upon the application of ultrasonic vibratory energy (Fig. 39; Paras. [0455-0456]).

Referring to claim 59, Bonutti discloses wherein said bondable material is bone cement (material 802; Par. [0675]).

Referring to claim 60, Bonutti discloses wherein said fastening implant further includes a widened head portion at said trailing end (Fig. 36).

Referring to claim 62, Bonutti discloses including a radiopaque marker (not shown) oriented in connection to said fastening implant to indicate a position of said channel, whereby said radiopaque marker is operative to indicate a position of said channel within the body after said fastening implant is implanted within the body, and radio imaging is applied to the body (Paras. [0386], [0760] and [0790]).

Referring to claim 63, Bonutti discloses wherein said channel contains a bondable material (Figs. 38-39; 850).

Referring to claim 64, Bonutti discloses wherein said fastening implant is an intramedullary device (Fig. 40).

Referring to claim 65, Bonutti discloses further including a connecting implant (840), said connecting implant adapted to matingly engage and connect to said fastening implant (Figs. 38-39 and 40A), said connecting implant further adapted to connect to a therapeutic implant (plate 884; Fig. 40A), said connecting implant thereby operative to connect said therapeutic implant to the body (Fig. 40A).

Referring to claim 66, Bonutti discloses wherein said connecting implant is threadably engagable to said fastening implant (Fig. 39).

Referring to claim 68, Bonutti discloses wherein said channel may contain or be filled with a therapeutic substance (Paras. [0208] and [0411-0412]).

Referring to claim 69, Bonutti discloses further including a cap (304; Fig. 19) operative to close said channel (bore 306 and anchor channel 310; Paras. [0472-0473]).

Referring to claim 70, Bonutti discloses wherein said cap is formed with a bondable material (Par. [0472]).

Referring to claim 71, Bonutti discloses wherein said cap is permeable by a material placed within said channel, and is thereby operative to permit a passage of material from said channel to the body (Par. [0472]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025263

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Claim 61 lacks an inventive step under PCT Article 33(3) as being obvious over Bonutti.
Referring to claim 61, Bonutti discloses the system of claim 56. However, Bonutti does not explicitly disclose wherein said coating of bondable material has a non-uniform thickness along a length of said fastening implant.
However, the thickness along the length of the implant could vary depending on the application of the implant and the depth of installation. In order to create a stronger bond between the fastener and the body at the connecting point more bondable material may be utilized. The distribution of the bondable material along the length of the implant is merely a design choice and would only require routine skill in the art.
Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the bondable coating material of the fastening implant of Bonutti to include wherein said coating of bondable material has a non-uniform thickness along a length of said fastening implant, for the purpose of establishing relatively stronger bond at specific locations between the implant and the body along the length of the implant.

Claims 67 lacks an inventive step under PCT Article 33(3) as being obvious over Bonutti in view of Alacreu et al., (Hereinafter referred to as "Alacreu").
Referring to claim 67, Bonutti discloses wherein said connecting implant includes a post (middle portion of fastener 840 between threads 848 and unmarked end cap; Fig. 38), and wherein said therapeutic implant includes an aperture (the unmarked aperture of plate 884 as displayed in Fig. 40A which is similar to plate 2046 in Fig. 74B), and wherein a portion of said post is passable through said aperture (Figs. 40A and 74B). However, Bonutti does not explicitly disclose the portion of said post passing through said aperture being expandable, whereby an expanded portion of said post may be made wider than said aperture, whereby said connecting implant may be secured to said therapeutic implant.
However, Alacreu teaches a vertebral fusion system (Figs. 1 and 3) comprising a plate (4) and expandable anchoring screw (6; Fig. 1) wherein a portion of a post (the midsection of screw 6) passing through the plate aperture (16; Figs. 6-7) is being expandable (Figs. 1 and 9), whereby an expanded portion of said post may be made wider than said aperture, whereby said connecting implant may be secured to said therapeutic implant (Page 10, lines 19-25 and Page 11, lines 6-21).
Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the fastener implant of Bonutti to include the portion of said post passing through said aperture being expandable, whereby an expanded portion of said post may be made wider than said aperture, whereby said connecting implant may be secured to said therapeutic implant, as taught by Alacreu for the purpose of securely locking the post within the therapeutic plate.

Claims 1-71 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.